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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SAEED, KAMAL A

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1626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/820,453	BECKER ET AL.	
	Examiner	Art Unit	
	Kamal A. Saeed	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *28-40* is/are withdrawn from consideration.

5)☒ Claim(s) *1-22* is/are allowed.

6)☐ Claim(s) *23-25* is/are rejected.

7)☒ Claim(s) *26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

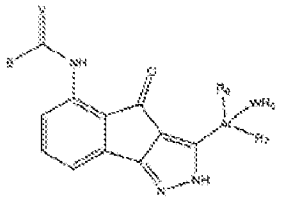
1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

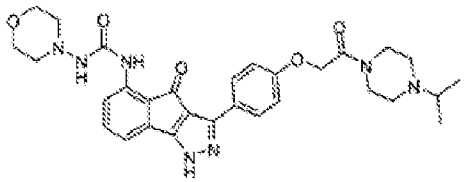
Claims 1-41 are currently pending in this Application. Claims 23-41 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention

Response to Restriction

Applicants' election with traverse of Group I, claim 1-22, drawn to the compounds



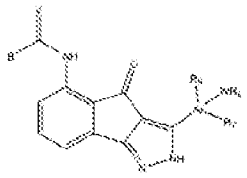
represented by Formula and the specific compound



as single disclosed species in response filed April 26, 2007 is acknowledged.

Applicant's arguments regarding the restriction within Group I have been found persuasive and the full scope of the invention of Group I have been examined.

The scope of the invention of the elected subject matter is as follows:



Compounds of formula I, depicted in claim 1, wherein all the variables are as defined in claim 1.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Previous Rejections

Claims 1 and 11, were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants ameded the claims by deleting the terms 'isomers" and "N-oxides" from the claims. Therefore, the rejections is hereby withdrawn.

Rejeonder

Since the product of the elected group is found allowable, claims 23-27 and 41 directed to a method of use have been rejoined with the allowed product.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 23 and 24 rejected under 35 U.S.C. 112, as failing to comply with the enablement requirement, because the Specification, while being enabling for inhibiting CDK for "treating" certain diseases, does not reasonably provide enablement for treating any type of cell proliferative disease, as claimed. Claim 25 is directed to method of reating all viral infection

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

7. The applicable rule is that "Each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description." MPEP 2163(II)(1), citing In re Morris, 127 F.3d 1048, 1053-1054; 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). Applying this rule to Claim 23-25 the scope of diseases claimed to be treated would thereby include all types and kinds of viral infections and cancerous tumors, including such diverse types as breast cancer, prostate cancer, lung cancer, pancreatic cancer, renal cancer, etc. However, the Specification only describes a few *in vitro* studies demonstrating the instant compounds' inhibitory effect on cdk kinase, and demonstrating concentrations of the claimed compounds needed to suppress 50% of cell proliferation (IC_{50} values). Given the scope of the many types of viral infections and cancerous tumors included within claim 23-25, their varied etiologies, and the diversity of their patient populations, the disclosure in the Specification is insufficient to permit a person skilled in the art to employ a compound "treating all vial infections and all cancers."

The Nature of the Invention

Claims 23-25 are directed to a method for treating a hyperproliferative disorder , method

for inhibiting proliferation cell and method of treating viral infections in a patient by administering the instant claimed compound.

The Breadth of Claims

The text of Claim 23-25 does not specify or enumerate those many types of hyperproliferative disorders that would fall within the scope of "solid tumour disease." As noted earlier, the applicable rule is that "Each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description." In view of this rule, claim 23 and 24 may be reasonably interpreted to encompass all forms of cancerous tumors, as neither the claims themselves nor the Specification expressly defines a closed set of illnesses defined as "solid tumour diseas" therefore claim 21 encompasses an open-ended set of types of cancers or cancerous tumors. The scope of claim 21 reasonably encompasses such a broad spectrum of types of cancerous tumors that it is unreasonable to believe, on its face, that a particular chemical compound could be used "for inhibiting a tumor" of so many different types, in the absence of supporting scientific data or references in the disclosure to the contrary. Due to the unpredictable nature of cancer and the fact that over 3,000 different cancers exist, the various types of cancers have different causative agents, involve different cellular mechanisms, and differ in treatment protocol, thus no single compound exists presently that is known to treat *all* cancers as a blanket therapeutic. Furthermore, the Merck® manual currently has many cancer treating agents (over 12,000 compounds), yet they are only known to treat a few types of cancer each.

The State of the Prior Art

Claim recites a method of treating such varied forms of unrelated cancerous tumors as

breast cancer, lung cancer, prostate cancer, malignant melanoma, colorectal cancers, bladder cancer, etc. However, subsequent to the time of this application, as stated above, no compound is known to treat *all* cancers or *all* cancerous tumors as a blanket therapeutic.

As stated in the Specification, the instant compounds possess cdk inhibitory properties demonstrated *in vitro,* with inhibitory effects on cdk activity in human cell lines *in vitro*.

The Relative Skill of Those in the Art

Those practitioners who treat cancerous tumors of any type (medical clinicians, pharmacists and/or pharmaceutical chemists) and viral infections presumably would be highly skilled in the art.

The Predictability or Unpredictability of the Art

Even though the instant compounds have been identified as having the ability to inhibit the activity of cdk for treating certain proliferative diseases, as a practical matter their use as therapeutic agents for treating solid tumors remains unpredictable. It is noted that the pharmaceutical art generally is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The court in In re Fisher, 427 F.2d 833, 839,. 166 USPQ 18, 24 (CCPA 1970) held that, "in cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." In other words, the more unpredictable an area the more specific enablement is needed in order to satisfy the statute. In the instant case, it has not yet been established in the art that antiproliferative activity would be effective, or even desirable, across the broad range of types of cancerous tumors.

The nature of the pharmaceutical arts is such that it involves screening *in vitro* and *in vivo*

to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability, even in view of the high level of skill in the art. This unpredictability is more pronounced where the diseases disclosed in the Specification are as complex and diverse in etiology and patient populations as the many different types of cancer disclosed in this application. As to treating solid tumour diseases including various cancerous tumors by use of cdk inhibitor compounds, the Examiner was not able to locate prospective clinical studies in the art demonstrating blanket treatment or prevention of all types of cancerous tumors, so there were no benchmarks against which to compare the efficacy of the claimed chemical compounds. However, the Examiner did find evidence that cdk inhibitors are effective for inhibiting angiogenesis which might suggest that the compounds would also be effective for inhibiting the growth of certain *specific* types of solid tumors. In light of the highly unpredictable nature of this art, the Specification failed to disclose facts which would enable the skilled artisan to use the compounds to prevent or treat cancerous tumors without undue experimentation.

The Quantity of Experimentation Necessary

When considering the claim for a method of treating the broad array of types of solid tumors and viral infections using compounds of the instant claims, in the context of the state of the art at the time of the invention, the absence of direction of working examples in the Specification, and the unpredictability of using the claimed invention for treating or preventing cancerous tumors, someone skilled in the art would require an undue quantity of experimentation even to select which of the many compounds would be useful to treat prevent solid tumor diseases, or to select those persons (presumably both with or without tumors or cancer) who would benefit by administration of the claimed invention, and the skilled artisan would have

little assurance of success.

One skilled in the art would require an undue quantity of experimentation to make or use the claimed agent for treating all of the claimed types of solid or cancerous tumor diseases; however, it would not require an undue quantity of experimentation for the skilled artisan to use the invention for "inhibiting the growth of" certain *specific* types of viral infection and tumours that are **supported** in Applicants' disclosure or the prior art, with a reasonable likelihood of success.

1. Claim 41 provides for the use of compounds, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim41 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Objections

Claim 26 is objected to for depending on a rejected base claim.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal A Saeed, Ph.D. whose telephone number is (571) 272-0705. The examiner can normally be reached on M-T 7:00 AM- 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signiture, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

/Kamal A Saeed, Ph.D./

Primary Examiner, Art Unit 1626